

CLAIMS

1. An *in vitro* method of screening an individual for metastatic colorectal cancer cells or primary and/or metastatic stomach or esophageal cancer cells comprising the steps of examining a sample of extraintestinal tissue and/or body fluids from an individual to
- 5 determine whether CDX2 is being expressed by cells in said sample wherein expression of said CDX2 indicates a possibility of metastatic colorectal cancer cells or primary and/or metastatic stomach or esophageal cancer cells in said sample.
2. The method of claim 1 wherein expression of said CDX2 by said cells is determined by detecting the presence of CDX2 gene transcription product.
- 10 3. The method of claim 1 wherein expression of said CDX2 by said cells is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom.
4. The method of claim 1 wherein expression of said CDX2 by said cells is determined by immunoassay wherein said sample is contacted with antibodies that
- 15 specifically bind to CDX2 gene translation product.
5. The method of claim 1 wherein said sample is body fluid.
6. The method of claim 1 wherein said sample is blood.
7. The method of claim 1 wherein said sample is lymphatic tissue and/or fluid.
8. The method of claim 1 wherein said sample is a lymph node sample.
- 20 9. The method of claim 1 wherein the individual has previously been diagnosed with having colorectal, stomach or esophageal cancer.

10. The method of claim 1 wherein the individual has previously been diagnosed with and treated for colorectal, stomach or esophageal cancer
11. An *in vitro* method of screening an individual for metastatic colorectal cancer cells or primary and/or metastatic stomach or esophageal cancer cells comprising the steps
5 of examining a sample of extraintestinal tissue and/or body fluids from an individual to determine whether CDX2 gene transcription or translation product is present in said sample wherein the presence of CDX2 gene transcription or translation product in said sample indicates that the individual may have metastatic colorectal cancer cells or primary and/or metastatic stomach or esophageal cancer cells in said sample.
- 10 12. The method of claim 10 comprising the steps of examining a sample of extraintestinal tissue and/or body fluids from an individual to determine whether CDX2 gene transcription product is present in said sample.
13. The method of claim 12 wherein the presence of CDX2 gene transcription
15 product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom.
14. The method of claim 11 wherein the presence of CDX2 gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to CDX2 gene translation product.
15. The method of claim 11 wherein said sample is body fluid.
- 20 16. The method of claim 11 wherein said sample is blood.
17. The method of claim 11 wherein said sample is lymphatic tissue and/or fluid.
18. The method of claim 11 wherein said sample is a lymph node sample.

19. The method of claim 11 wherein the individual has previously been diagnosed with having colorectal, stomach or esophageal cancer.
20. The method of claim 11 wherein the individual has previously been diagnosed with and treated for colorectal, stomach or esophageal cancer
- 5 21. An *in vitro* method of confirming that a tumor cell removed from a patient suspected of having colorectal, stomach or esophageal cancer cells is a colorectal, stomach or esophageal tumor cell comprising the step of determining whether a tumor cell expresses CDX2 wherein expression of CDX2 indicates that the tumor cell is a stomach or esophageal tumor cell.
- 10 22. The method of claim 21 wherein expression of CDX2 by said tumor cell is determined by detecting the presence of CDX2 gene transcription product.
23. The method of claim 21 wherein expression of CDX2 by said tumor cell is determined by polymerase chain reaction wherein mRNA from said tumor cell or cDNA generated therefrom is contacted with primers that selectively amplify CDX2 gene
- 15 transcript or cDNA generated therefrom.
24. The method of claim 21 wherein expression of CDX2 by said tumor cell is determined by immunoassay wherein protein from said tumor cell is contacted with antibodies that specifically bind to CDX2 gene translation product.
25. A method of diagnosing an individual who has stomach cancer comprising
- 20 the steps of examining a sample of stomach tissue to detect the presence of CDX2 transcript or translation product wherein the presence of CDX2 transcript or translation product in a stomach sample indicates stomach cancer.

26. The method of claim 25 comprising the steps of examining said sample of stomach tissue to determine whether CDX2 gene transcription product is present in said sample.

Sub A2
5 27. The method of claim 26 wherein the presence of CDX2 gene transcription product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom.

28. The method of claim 26 wherein the presence of CDX2 gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to CDX2 gene translation product.

Sub A3
10 29. A method of diagnosing an individual who has esophageal cancer comprising the steps of examining a sample of esophagus tissue to detect the presence of CDX2 transcript or translation product wherein the presence of CDX2 transcript or translation product in an esophageal sample indicates esophageal cancer.

30. The method of claim 29 comprising the steps of examining said sample of esophageal tissue to determine whether CDX2 gene transcription product is present in said sample.
15

Sub A4
31. The method of claim 30 wherein the presence of CDX2 gene transcription product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom.

20 32. The method of claim 29 wherein the presence of CDX2 gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to CDX2 gene translation product.

33. A kit for diagnosing an individual who has colorectal, stomach and/or esophageal cancer comprising either:

a) a container comprising polymerase chain reaction primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom;

5 and one or more of:

a container comprising a positive PCR assay control sample,
a container comprising a negative PCR assay control sample,
instructions for obtaining and/or processing a sample,
instructions for performing a PCR diagnostic assay, and
10 photographs or illustrations depicting a positive result and/or a negative result of a PCR diagnostic assay; or

b) a container comprising antibodies that specifically bind to CDX2 gene translation product;

and one or more of:

15 a container comprising a positive immunoassay control sample,
a container comprising a negative immunoassay control sample,

instructions for obtaining and/or processing a sample,
instructions for performing an immuno diagnostic assay, and
20 photographs or illustrations depicting a positive result and/or a negative result of an immuno diagnostic assay.